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WO 00/25588 A1

(54) Title: ANTI-SNORING COMPOSITION

(57) Abstract: The present invention is directed to a compound for preventing snoring. Essentially, the compound includes various natural oils such as almond oil, olive oil, sunflower oil, and peppermint oil, which serve to lubricate the soft tissue including the uvula and soft palette during sleep. In that manner, the oils dampen the friction of the soft tissue and diminish the noise associated with snoring. The present anti-snoring compound also includes a magnesium-based compound, which helps the oils cling to the soft tissue. If desired, vitamins B<sub>6</sub>, C and E are also included in the formulation of the present anti-snoring composition, primarily for the health benefit derived from them.

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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>7</sup> :</b> <b>A01N 65/00, A61K 35/78, 39/385</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 00/25588</b> <b>(43) International Publication Date:</b> 11 May 2000 (11.05.00)
<b>(21) International Application Number:</b> PCT/US99/25391 <b>(22) International Filing Date:</b> 28 October 1999 (28.10.99)  <b>(30) Priority Data:</b> 60/106,120                      29 October 1998 (29.10.98)                      US  <b>(71) Applicants:</b> MED GEN INC. [US/US]; Suite 230, 2501 Davie Road, Davie, FL 33317 (US). INNOVATIVE CHEMICAL CORPORATION [US/US]; 55 Woodridge Drive, Amherst, NY 14228 (US).  <b>(72) Inventors:</b> MITCHELL, Paul, S.; 23086 Island View Drive #7, Boca Raton, FL 33416 (US). ROBINSON, Gary; 139 South Ellicott Road, Amherst, NY 14228 (US). KRAVITZ, Paul, B.; 4320 N.W. 101 Drive, Coral Springs, FL 33065 (US).  <b>(74) Agents:</b> SCALISE, Michael, F. et al.; Hodgson, Russ, Andrews, Woods & Goodyear, LLP, Suite 2000, One M & T Plaza, Buffalo, NY 14203-2391 (US).		<b>(81) Designated States:</b> AU, KR, NO, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> ANTI-SNORING COMPOSITION		
<b>(57) Abstract</b>  The present invention is directed to a compound for preventing snoring. Essentially, the compound includes various natural oils such as almond oil, olive oil, sunflower oil, and peppermint oil, which serve to lubricate the soft tissue including the uvula and soft palette during sleep. In that manner, the oils dampen the friction of the soft tissue and diminish the noise associated with snoring. The present anti-snoring compound also includes a magnesium-based compound, which helps the oils cling to the soft tissue. If desired, vitamins B <sub>6</sub> , C and E are also included in the formulation of the present anti-snoring composition, primarily for the health benefit derived from them.		

## ANTI-SNORING COMPOSITION

## 5 CROSS-REFERENCE TO RELATED APPLICATION

The present application claims priority based on provisional application Serial No. 60/106,120, filed October 29, 1998.

10

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

15 The present invention relates to an anti-snoring composition.

## 2. Prior Art

20 A National Family Opinion poll conducted in July, 1994 revealed that 90 million Americans over the age of 18 snore and 37 million of those are considered habitual snorers. Interestingly, it was found that snoring is almost twice as common in men as in women. The  
25 likelihood of developing a snoring condition also increases with age. Approximately 30% of American males snore at age 30, and about 40% of all Americans snore by the age of 50. Being that there are approximately 290 million Americans, and about 50% are over 50, there are  
30 more than 58 million suffering snoring Americans over 50 years of age. Although the problem is common and often not fatal, it is, nonetheless, a medical condition that should be attended to.

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narrowing of the airway and the subsequent snoring is greatest during sleep because the throat muscles, tissues and tongue are relaxed, causing the air passageway to narrow.

5        Sleeping on the back also can cause snoring in that it deprives a person of the normal sleep reflex. Sleeping on the side causes a natural reflex which acts to decongest the nostril on the opposite side, allowing easier breathing through the nasal passage. Sleeping on  
10 the back disturbs this normal reflex.

      There are some people who during sleep suffer from a complete collapse of the airway leading to the lungs and, consequently, the supply of the air to the lungs is totally blocked off. When this occurs it is called  
15 sleep apnea. An apnea is defined as an absence of air flow for about 10 seconds or more. A person with a typical case of sleep apnea has a blockage of breathing of about 10 to 60 seconds at a frequency of five times per hour. Despite the lack of oxygen, the sleeping  
20 person is constantly trying to bring air into the lungs, forcing a complete collapse of the tissues of the throat and causing a gasping or snoring-type noise. During this process, the person will have a dangerous drop in blood pressure. This situation can become potentially  
25 dangerous.

      Under normal circumstances, the apnea is terminated by an arousal, and for the most part is so brief it is hardly remembered. The arousal increases the tone of the muscles in the throat and tongue, thereby releasing  
30 the airway blockage and creating a loud grunt or snore. This is usually followed by a period of rapid breathing and again a new apnea occurs.

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snoring and providing the person with a relaxed and prolonged nights sleep.

The present anti-snoring composition is typically in the form of an aerosol mist that is sprayed on the back of the throat, tongue and uvula to coat these soft tissues with a lubricating composition which allows for up to ten hours of restful silent sleep.

The ingredients of the present anti-snoring composition are listed in Table 1 below. The composition is comprised of at least one of the group of almond oil, olive oil, peppermint oil, sesame oil and sunflower oil. These oils serve to lubricate the soft tissues in the mouth and throat including the uvula and the soft palate during sleep. Magnesium is important to help retain the various oils on the soft tissue for up to ten hours. In the present invention magnesium is preferably provided in the form of carrageenan (*chondrus crispus*). This compound is a plant material obtained from various members of the Gigarthineae of Solieriaceae families of red seaweed, Rodophyceae. It is marketed under various brand names of Aquaron, Gencarin, Seaspen and Viscarin. Another preferred compound is magnesium aluminum silicate, which is a complex silicate refined from naturally occurring minerals. It is marketed under various brand names including Gel White, Magnabrite and Veegum. The magnesium compounds have an encapsulating effect that help retain the oils on the soft tissues in the throat throughout the sleep period to continuously prevent the noise associated with snoring. It should be pointed out that while all of the listed oils are preferred for the present composition, they are not all required. What is needed is at least one of the listed

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hormones. Vitamin C also helps to prevent cancer and infection and enhances immunity.

Vitamin E is an antioxidant which is important in preventing cancer and cardiovascular disease. It is  
5 widely used to promote blood clotting and healing, and to reduce blood pressure.

The following example describes the manner and process of an anti-snoring composition according to the present invention, and it sets forth the best mode  
10 contemplated by the inventors for carrying out the invention, but it is not to be construed as limiting.

#### EXAMPLE

15 A double blind study was conducted under medical and clinical criteria and guidelines for such tests. The study had a total of fifty participants. All subjects were in good health except that they experience snoring problems. None of the test subjects was  
20 currently taking medication or had a surgical condition which would interfere with the integrity of the study. None of the test subjects had a history of neurological disorders, cardiac, pulmonary, gastrointestinal, liver or kidney disease, or other clinically important  
25 diseases.

None of the subjects or the physician administering the study was aware of when and to whom the anti-snoring composition or placebo was being dispensed. The anti-snoring composition was dispensed along with  
30 instructions for use, and an evaluation sheet.

The present anti-snoring composition was used over a one week period. Most participants had not used any other anti-snoring product, and none of the participants

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5. Q: Has anyone complained about your snoring?

	A:		<u>Participants</u>		<u>Percentage</u>
5		Yes	36	-	92%
		No	3	-	8%

6. Q: Describe your snoring prior to any treatment.

10 A: a) Loudness (scale from 0=none, 1=minimal to 5 loudest)

		<u>Participants</u>	<u>Percentage</u>
	0	0	0%
	1	5	13%
15	2	3	8%
	3	9	23%
	4	9	23% = 79% - loudness complaints
	5	13	33%

20

b) Disruptive (scale from 0=none, 1= minimal to 5 loudest)

		<u>Participants</u>	<u>Percentage</u>
	0	0	0%
25	1	6	15%
	2	5	13%
	3	6	15%
	4	10	26% = 72% -disruptive complaints
30	5	12	31%

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9. Q: How many times a night does your bed partner's snoring awaken you?

		<u>0</u>	<u>1-2</u>	<u>3-4</u>	<u>5</u>
A:	a) with no treatment	10	14	13	4
5	b) with present anti-snoring composition	23	10	2	1 > 92% improvement in sleeping w/present composition

10. Q: Please evaluate you partner when using the present anti-snoring composition (Table 2) and without (Table 3).

Table 2  
Best to Worst

15	With Present Composition	1	2	3	4	5
	1.Mouth Dryness	11	14	5	0	0
	2.Sleep Quality	11	9	7	5	0
	3.# of Hrs slept	5-9 HRS.				
20	4.# of Times Awaken	11	9	4	0	0
	5.Side Effects	No Side Effect				

Table 3  
Best to Worst

25	WITHOUT	1	2	3	4	5
	1.Mouth Dryness	1	3	5	4	3
	2.Sleep Quality	2	5	5	5	0
30	3.# of Hrs slept	3-6 HRS.				
	4.# of Times Awaken	3	3	1	2	0
	5.Side Effects	No Side Effect				

35 11. Q: List side effects.

A: No side effect detected.



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	<u>Participants</u>	<u>Percentage</u>
	0	0%
	1	36%
	2	10%
5	3	18%
	4	0% = 54% - loudness complaints
	5	36%

10 b) Disruptive (scale from 0=none, 1=minimal to 5=loudest)

	<u>Participants</u>	<u>Percentage</u>
	0	10%
	1	36%
15	2	18%
	3	0%
	4	18% 36% - disruptive complaints
	5	18%

20

7. Q: Describe your snoring when using the present anti-snoring composition?

A: a) Loudness (scale from 0=none, 1=minimal to 5 loudest)

	<u>Participants</u>	<u>Percentage</u>
25	0	27%
	1	10% =68% improvement
	2	31%
	3	18%
30	4	0%
	5	10%

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Table 5  
Best to Worst

WITHOUT SPRAY	1	2	3	4	5
1.Mouth Dryness	1	2	1	0	2
2.Sleep Quality	3	2	1	0	0
3.# of Hrs slept	6-8 HRS.				
4.# of Times Awaken	2	1	0	0	0
5.Side Effects	No Side Effects				

10

11. Q: List side effects:

A: No side effects detected.

15

It should be pointed out that the group administered the placebo experienced some degree of improvement in the sleeping test, however, not to the extent realized by the group administered the present anti-snoring composition. Also, in the Example under the section setting forth the results of the participants given a placebo, there are references to use of the present anti-snoring composition. In fact, these participants did not receive the present composition because they were the placebo group. Nonetheless, they believed they were being treated with the present composition, thus the somewhat improved results.

20

25

It is appreciated that various modifications to the present inventive concepts described herein may be apparent to those of ordinary skill in the art without departing from the spirit and scope of the present invention as defined by the herein appended claims.

30

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8. The composition of claim 1 wherein the magnesium-based compound is selected from carrageenan and magnesium aluminum silicate.

9. A method for preventing snoring, comprising  
5 the steps of:

a) providing a composition comprising at least one natural oil and a magnesium-based compound; and

10 b) spraying an aerosol mist of the composition on the back of the throat, tongue and uvula to coat them before sleeping.

10. The method of claim 9 including selecting the natural oil from the group consisting of olive oil,  
15 almond oil, peppermint oil, sesame oil and sunflower oil, and mixtures thereof.

11. The method of claim 9 wherein the olive oil is present, by volume, in a range of about 3.0% to about  
20 11.0%.

12. The method of claim 9 wherein the almond oil is present, by volume, in a range of about 0.4% to about  
25 2.0%.

13. The method of claim 9 wherein the peppermint oil is present, by volume, in a range of about 0.5% to about 2.0%.

14. The method of claim 9 wherein the sesame oil is present, by volume, in a range of about 1.0% to about  
30 5.0%.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/25391

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 65/00; A61K 35/78, 39/385

US CL : 424/195.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/195.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,480,865 (KINGHAM) 02 January 1996 (02.01.96), see column 3, last paragraph; column 6, lines 27-34; Examples 3, 4, 5, and 6.	1, 2, 7, 8 ----- 3, 4, 6
X --- Y	US 4,606,771 A (MUKOHYAMA et al.) 19 August 1986 (19.08.86), see column 4, lines 58-66 and column 5, lines 4-5.	1,2,8 ----- 3, 6, 9, 10, 11 ,14,16
Y	US 4,876,283 A (REICHERT) 24 October 1989 (24.10.89), see column 1, lines 41-45; column 2, lines 67-68; column 5, lines 51-55.	1-16
Y	US 4,831,013 A (FRANCIS) 16 May 1989 (16.05.89), see column 1, lines 59-64; column 9, line 32-33.	1,8,9,16



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document published on or after the international filing date

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\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\*

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\*

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\*

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

\*A\*

document member of the same patent family

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02 FEBRUARY 2000

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# INTERNATIONAL SEARCH REPORT

International application No.  
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## B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

USPT, JPAB, EPAB, DWPI on WEST, REGISTRY, BIOSIS, CAPLUS, PROMT, SCISEARCH on STN  
search terms: oil, snoring, olive, almond, peppermint, sesame, sunflower, carrageenan, magnesium aluminum silicate